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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,816	12/28/2000	Tatsuro Kawamura	43888-092	3440

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EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/749,816

Applicant(s)

KAWAMURA, TATSUROU

Examiner

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-12 and 14-28 is/are allowed.
- 6) ☒ Claim(s) 1 and 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,264,589 to Corey (herein referred to as "Corey '589) in view of USP 4,485,176 to Bollin, Jr. et al. (herein referred to as "Bollin").

Corey '589 teaches that a known method for the determination of the presence of protein consists of measuring turbidity following sample acidification. According to this known method, the turbidity of the sample is measured using a spectrophotometer following the addition of a protein-precipitating agent, generally an acidifying agent, to the sample. The calculated turbidity of the sample is compared to the spectrophotometric standard curves to determine the presence of protein in the sample. Common precipitating agents include sulfosalicylic acid, trichloroacetic acid and tannic acid. See col. 1, lines 45-55.

Corey '589 does not expressly teach measuring intensity before and after the addition of tannic acid. However, it would have been obvious to one of ordinary skill in the art to measure the absorbancy before and after the addition of tannic acid in order to generate the spectrophotometric standard curve used to calibrate protein amount. Measuring the sample before the addition of tannic acid would serve as a reference sample and eradicate any unwanted background from the sample. It is well appreciated in the art that a "zeroing" sample be used to calibrate the spectrophotometer prior to subsequent measure of samples. This assertion is

further exemplified by Bollin, comprising a method of measuring the protein concentration in a sample by differentiating between samples containing turbidity and samples wherein the turbidity-causing reagent was not added (blank). This blank is "particularly useful for the measurement of protein" in turbidity methods because it can "help reduce assay interference" from sample chromogens, bubbles, and the like. Bollin establishes that it is well within the skill of the art to have turbidimetric methods that include both measurement of the absorbance of protein samples both before and after the presence of turbidity.

Further, with regard to claim 7, while Corey '589 does not disclose such a correction procedure, it would have been well within the skill of the art to recognize procedural problems that may lead to a skewed result and have some means to compare the result to that indicative of a problem.

#### *Response to Arguments*

2. Applicant's arguments filed 10/22/2003 have been fully considered but they are not persuasive. The Bollin reference has been incorporated into the instant rejection only to further corroborate the Examiner's assertions, per Applicant's request.

Applicant has made several arguments concerning the properness of the standing Corey '589 rejection. Applicant first makes the point that the object of the present invention is to allow determination of the quantity of a sample whose concentration is unknown. This statement may be true, however, the instant claims are not drafted in such a way to preclude the addition of other steps. Thus, the new combination of Corey '589 & Bollin serves to exemplify that it is known in the prior art to have turbidimetric methods that include both unknown protein samples

and known standard samples by which to comparatively quantify the concentration of the unknown. For instance, in the Bollin method, col. 3, lines 5-9, it is mentioned that the difference between the blank absorbance and test absorbance are compared to those obtained from processing a series of known standards. The test absorbance is therefore unknown and some of the other samples are known. Applicant should also note that the instant claims do not require that the sample be unknown.

Applicant further argues that generating a standard curve is not equivalent to measuring protein concentration. However, it is the Examiner's position that the Bollin reference demonstrates that standard curves can serve to show both a relationship between the known protein concentration and detected light intensity and measure protein concentration of a test sample having an unknown protein concentration. See Example 1, col. 3, line 65-col. 4, line 2.

Lastly, Applicant has argued that the cited prior art does not recognize or consider the problems associated with inherent turbidity in protein measurement processes. However, this is not a limitation of the claims and does not have to be addressed by the prior art if there is another reason for measuring turbidity prior to the addition of the reagent. The Bollin reference teaches that use of a blank absorbance can help reduce interference in measuring turbidity. Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, over Corey '569 in view of Bollin.

*Allowable Subject Matter*

3. Claims 8-12 and 14-28 are allowed.

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4. Claims 2, 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Monique T. Cole  
Examiner  
Art Unit 1743

MC *MC*

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700